BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images may include (but are not limited to):

- BLACK BORDERS
- TEXT CUT OFF AT TOP, BOTTOM OR SIDES
- FADED TEXT
- ILLEGIBLE TEXT
- SKEWED/SLANTED IMAGES
- COLORED PHOTOS
- BLACK OR VERY BLACK AND WHITE DARK PHOTOS
- GRAY SCALE DOCUMENTS

IMAGES ARE BEST AVAILABLE COPY.

As rescanning documents *will not* correct images, please do not report the images to the Image Problem Mailbox.

(19) Europäisches Patentamt
European Patent Office
Office européen des brevets

(11) Publication number : **0 657 185 A2**

(12) EUROPEAN PATENT APPLICATION

(21) Application number : **94309221.3**

(51) Int. Cl.[6] : **A61N 1/36**

(22) Date of filing : **09.12.94**

(30) Priority : **09.12.93 US 164599**

(43) Date of publication of application :
14.06.95 Bulletin 95/24

(84) Designated Contracting States :
DE FR GB NL

(71) Applicant : **MEDTRONIC, INC.**
7000 Central Avenue N.E.
Minneapolis, Minnesota 55432-3576 (US)

(72) Inventor : **Camps, Antoine**
Eyserweg 36A
NL-6287 NE Eys Wittem (NL)

Inventor : **Dreessen, Chrit W.**
Houterend 7
NL-6171 CP Stein (NL)
Inventor : **Polz, Michel W.J.**
Lellestraat 36
NL-6466 XP Kerkrade (NL)
Inventor : **Grandjean, Pierre A.**
Rue A. Dekkers
B-4608 Warsage (BE)

(74) Representative : **Tomlinson, Kerry John et al**
Frank B. Dehn & Co.
European Patent Attorneys
Imperial House
15-19 Kingsway
London WC2B 6UZ (GB)

(54) Intramuscular lead having improved insertion.

(57) An intramuscular lead (100) for the electrical stimulation of muscle tissue. The improved lead has a needle (118) connected to a strand of suture (120), a coiled conductor (108) coupled to the strand by a reduced diameter portion of the coiled conductor, an insulative cover (101) over part of the coiled conductor ; and terminal connector means (102) coupled to the coiled conductor to provide a connection to a pulse generator. Through such a construction the lead may be more readily introduced through muscle tissue.

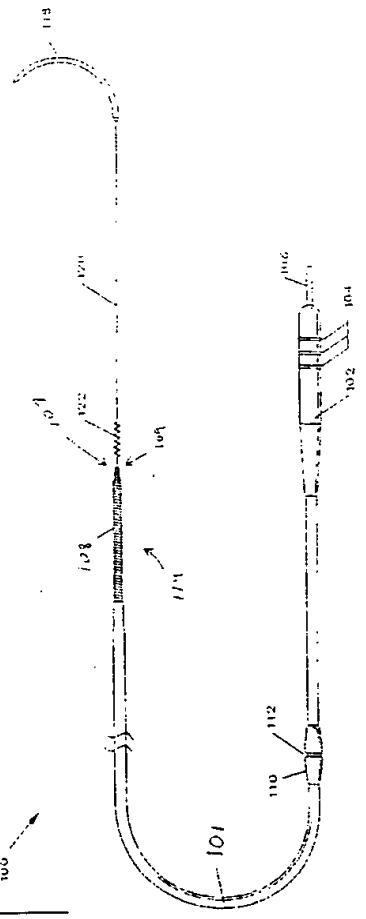


FIG. 2

EP 0 657 185 A2

The present invention generally relates to skeletal muscle stimulation, and more particularly, it relates to an intramuscular lead system having an improved electrode end for easier insertion.

Skeletal muscle tissue is often used to provide cardiac assistance. Such systems which utilize skeletal muscle tissue may be seen in U.S. Pat. Nos. 4,411,268, 4,813,952, and 4,735,205.

Such systems use a patient's own muscle tissue in conjunction with an implantable pulse generator to provide cardiac assistance. In comparison to presently available cardiac assist systems using wholly artificial structures, systems using a patient's skeletal muscle are extremely compact and energy efficient. Such cardiac assist systems, however, are not without limitations. One problem presented by the use of skeletal muscle power for cardiac assistance is the application of electrical stimulation signals to cause skeletal muscle contraction.

The electrical connection between an implantable pulse generator and the desired skeletal muscle is accomplished through a lead. Generally speaking a lead is a wire insulated along its length and having an electrode at one end and connectable to a pulse generator at its other end. Through a lead the electrical signal may be communicated to and from skeletal muscle tissue.

The earliest skeletal muscle powered cardiac assist systems used screw-in type leads for skeletal muscle stimulation. A major improvement to these leads is found in the use of steroid eluting pacing leads. U.S. Pat. No. 4,711,251 teaches the use of an endocardial pacing lead having steroid drug embedded in the distal tip. This embedded steroid drug treats the heart tissue immediately in contact with the pacing electrode. U.S. Pat. Nos. 4,506,680; 4,577,642; and 4,606,118 teach similar endocardial leads, all of which treat the electrode contact area with a steroid. United States Statutory Invention Registration No. H356 discloses an endocardial pacing lead suitable for epicardial insertion which elutes a steroid drug from the electrode.

A further improvement in intramuscular lead technology arose with the adaptation of heart wire technology for chronic pacing use. Typically such leads are constructed as follows: A connector assembly has a coiled connector attached thereto. The coiled connector is insulated along a part of its length while a suture runs throughout its inner lumen, from the connector assembly to an end. At the end of the suture a helical portion is formed, and a needle is attached to the end of the suture. The suture material is treated with a steroid drug, such as a glucocorticosteroid, along its entire length. Additional drugs which may be imbedded within the strand include antibiotics. Upon chronic implantation, the steroid drug is eluted from the suture material, thus treating possible tissue inflammation or damage caused by the implantation procedure or subsequent irritation.

One drawback to such a lead as presently configured is found at the conductor coil-suture interface. In designs presently in use the conductor coils are attached to the end of the suture by a crimp sleeve. In such a manner a tip electrode is formed. Because the suture is used to pull the electrode coil through muscle tissue during implantation, the crimp sleeve used to form a tip electrode, which has a larger diameter than either suture or electrode coil, creates friction. Such friction creates difficulties to the physician during implantation. For this reason a flexible, specifically designed lead having a relatively slender dimension at the conductor coil-suture interface is desired.

Briefly, the above and further objects and features of the present invention are realized by providing a new and improved intramuscular lead. The lead can be used to electrically stimulate muscle tissue that is configured for a cardiac assist system powered by surgically modified skeletal muscle tissue. The skeletal muscle is either wrapped about the heart itself, or about an auxiliary pumping chamber attached to the aorta. Electrical stimulation is supplied via the intramuscular lead to cause contraction of the skeletal muscle in synchrony with the natural or artificially paced heart rate and timed to obtain the desired hemodynamic effect. The improved lead has an electrode which is embedded in the skeletal muscle. The electrode is attached to a suture through a tapered or reduced diameter section of electrode coil. Through such a taper the electrode coil and suture are firmly joined.

Thus according to the invention there is provided an implantable lead for stimulation of a skeletal muscle comprising:

a needle;

a strand of suture connected to the needle;

a coiled conductor connected to the suture;

an insulative cover over part of the coiled conductor; and

terminal connector means coupled to the proximal end of the coiled conductor;

characterized in that the coiled conductor has a first coil portion and a second coil portion distal of the first, said second coil portion being of reduced diameter compared to the first and being coupled to a proximal portion of the suture.

The above and other objects, features and advantages of the present invention will be more apparent from the following more particular description of specific embodiments thereof, given by way of example only, and presented in conjunction with the accompanying drawings, wherein:

FIG. 1 is an schematic view of one configuration of a cardiac assist system;

FIG. 2 is a plan view of a chronically implantable stimulation lead according to the present invention;

FIG. 3 is an enlarged partial view of the coiled conductor-suture interface of a chronically implantable stimulation lead according to the prior art;

FIG. 4 is an enlarged partial view of the coiled conductor-suture interface of a chronically implantable stimulation lead according to the present invention;

FIG. 5 is a schematic view of the chronically implantable lead according to the present invention positioned in a skeletal muscle; and

FIG. 6 is an enlarged partial view of the coiled 35 conductor-suture interface of an alternative embodiment of a chronically implantable stimulation lead according to the present invention.

Cardiac assist systems utilizing electrically stimulated skeletal muscle supplement the heart in performing blood circulation. This assistance may take two basic forms. The first of these directly assists the natural heart by increasing aortic pressure at the same time as the heart. This may be implemented by wrapping the skeletal muscle about the heart. The second form increases circulatory system pressure during relaxation of the heart. The resulting increase in coronary perfusion provides the desired assistance to the heart by increasing myocardial oxygen supply.

With either form of cardiac assist, the heart is electrically sensed to ensure that the skeletal muscle is stimulated in the proper timing relationship to heart contractions. FIG. 1 shows a typical cardiac assist system 5 used to provide indirect assistance to the cardiac function. Specifically, this particular mode performs counter pulsation for enhanced perfusion. As discussed above, enhanced perfusion increases myocardial oxygen supply. It should be understood that this particular mode of cardiac assist is shown for the purpose of illustration only and not by way of limiting the scope of the present invention. Other modes of cardiac assist may be found in U.S. Pat. No. 4,813,952.

The human heart 10 is assisted by counterpulse contraction of skeletal muscle 22 and this results in the enhanced perfusion of cardiac tissue. Pulse generator 36 senses contractions of human heart 10 by lead 34. After a delay, pulse generator 36 sends stimulating pulses to skeletal muscle 22 via lead 100, thereby inducing contraction. As skeletal muscle 22 contracts, it reduces the diameter of chamber 20 which is coupled to aorta 12 via stub 16. This contraction increases aortic pressure, thereby improving perfusion through the coronary vascular system.

Skeletal muscle 22 must be conditioned to respond in the desired manner without or at least with minimal fatigue. U.S. Pat. No. 4,411,268 teaches such a method of conditioning.

FIG. 2 is a plan view of a chronically implantable lead 100 according to the present invention for stimulation of skeletal muscle 22 which powers cardiac assist system 5 of FIG. 1. The proximal end of lead 100 contains a connector 102 which couples to pulse generator 36 (not shown in FIG. 2). Connector 102 has sealing rings 104 which provide a fluid tight connection with pulse generator 36. A terminal pin 106 electrically couples lead 100 to pulse generator 36.

An insulating sheath 101 electrically insulates lead 100, and specifically coiled conductor 108. Coiled conductor 108 is coupled at one end to connector 102 and runs to its distal end 107. An electrode 114 is fashioned from an uninsulated portion of coiled conductor 108. Electrode 114, therefore, may be electrically connected to pulse generator 36.

A strand 120 of suture material of polypropylene or other polymer is attached to distal end 107 of coiled conductor 108. A curved surgical needle 118 is mechanically attached to the distal end of strand 120 of suture material.

A drug (such as a steroid and/or antibiotic) may be releasably imbedded within the polymer of strand 120. During the life of lead 100, this drug elutes out into the surrounding tissue at a predetermined rate. Preformed helix 122 is deformably molded into strand 120. Further description of imbedding a drug within strand 120 may be found in U.S. Patent No. 5,086,787. A detailed explanation of preformed helix 122 is found in U.S. Pat. No. 4,341,226.

FIG. 3 is an enlarged partial view of coiled 35 conductor-suture interface 109 of a stimulation lead 100 according to the prior art. As seen, coiled conductor 108 was attached to strand 120 through a crimp core 111. As seen, crimp core 111 presents a relatively bulky dimension, and specifically wider diameter, as compared to coiled conductor 108 and strand 120.

FIG. 4 is an enlarged partial view of coiled conductor-suture interface 109 of a stimulation lead 100 according to the present invention. As seen, coiled conductor 108 is attached to strand 120 through use of a reduced diameter portion or taper 113. Specifically, coiled conductor 108 is tapered to a dimension so that it firmly is attached to strand 120. Taper 113 may be accomplished in any known manner including swaging. Although not specifically depicted, the region of strand 120 engaged by taper 113 may be roughened so as to decrease its smoothness and enhance the grip of taper 113 thereto. Any suitable techniques may be used to provide such a rough surface including knurling strand 120. In addition, an adhesive may also be applied to strand 120 in the vicinity of taper 113 to enhance the grip of taper 113 thereto. Finally, to enhance the grip of taper 113 to strand 120 the coils of taper 113 may also be spot welded to one another once the strand and coils are joined.

FIG. 5 is a schematic view of lead 100 according to the present invention positioned in a skeletal muscle. As seen, needle 118 enters skeletal muscle 22 at puncture 128. It proceeds along path 132 and exits

skeletal muscle 22 at exit point 130. As needle 118 proceeds through muscle 22 it pulls strand 120 and coiled conductor 108 therewith. Because taper 113 is dimensioned as less than the widest dimension of coiled conductor 108, lead 100 may be inserted relatively easier than the lead featuring interface 109 shown in FIG. 3. Preformed helix 122 sustains electrode 114 in contact with skeletal muscle 22 at an appropriate position along path 132. If glucocorticosteroid is used, it elutes out from strand 120 and is able to reach all along path 132 including puncture 128 and exit point 130 to minimize acute and chronic inflammation.

FIG. 6 is an enlarged partial view of coiled conductor-suture interface 109 of an alternative embodiment for a chronically implantable stimulation lead according to the present invention. This embodiment is the same as that previously described with the exception of a retaining collar 115 positioned on taper 113. Collar 115 is stressed to provide additional clamping to strand 120 from coiled conductor 108. As seen collar 115 presents a cross-sectional dimension no larger than coiled conductor 108.

While the embodiment of the present invention has been described in particular application to cardiac assist technology, it will be understood the invention may be practised in other electrode technologies where the aforementioned characteristics are desirable, including neurological and muscle stimulation applications.

Furthermore, although the invention has been described in detail with particular reference to a preferred embodiment, it will be understood that variations and modifications can be effected within the scope of the invention which is defined by the following claims. Such modifications may include substituting elements or components which perform substantially the same function in substantially the same way to achieve substantially the same result for those described herein.

Claims

1. An implantable lead for stimulation of a skeletal muscle comprising:
   a needle;
   a strand of suture connected to the needle;
   a coiled conductor connected to the suture;
   an insulative cover over part of the coiled conductor; and
   terminal connector means coupled to the proximal end of the coiled conductor;
   characterized in that the coiled conductor has a first coil portion and a second coil portion distal of the first, said second coil portion being of reduced diameter compared to the first and being coupled to a proximal portion of the suture.

2. The lead according to claim 1 wherein the second section of the strand is smooth.

3. The lead according to claim 1 wherein the second section of the strand is roughened.

4. The lead according to claim 3 wherein the second section of the strand is knurled.

5. The lead according to claim 1, 2, 3 or 4 further comprising an adhesive on the second section of the strand.

6. The lead according to any preceding claim, wherein the strand is treated with elutable drug.

7. The lead according to claim 6, wherein the drug comprises a glucocorticosteroid.

8. The lead according to claim 6 or 7 wherein the drug comprises an antibiotic.

9. The lead according to any preceding claim further comprising a collar about the second portion of the coiled conductor.

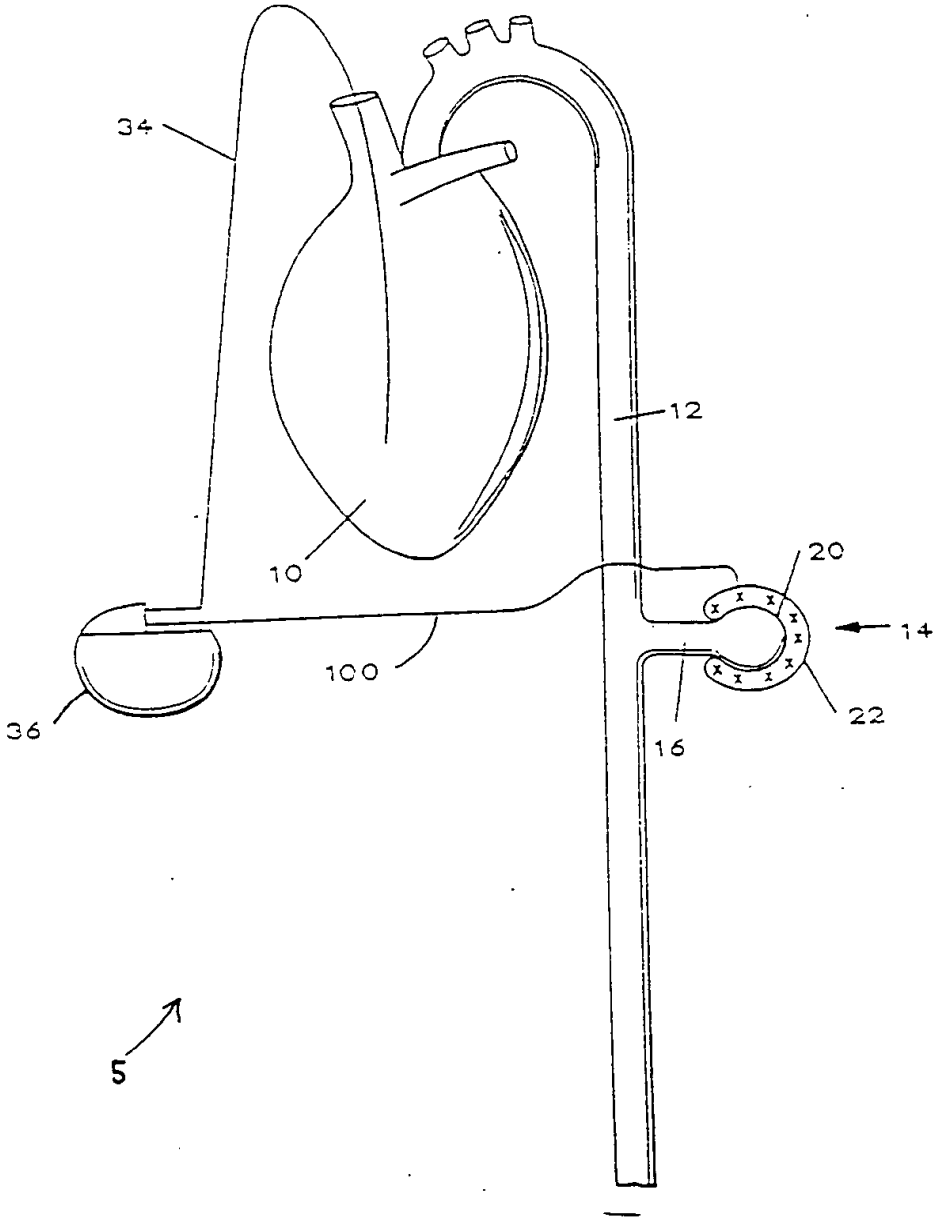


FIG. 1

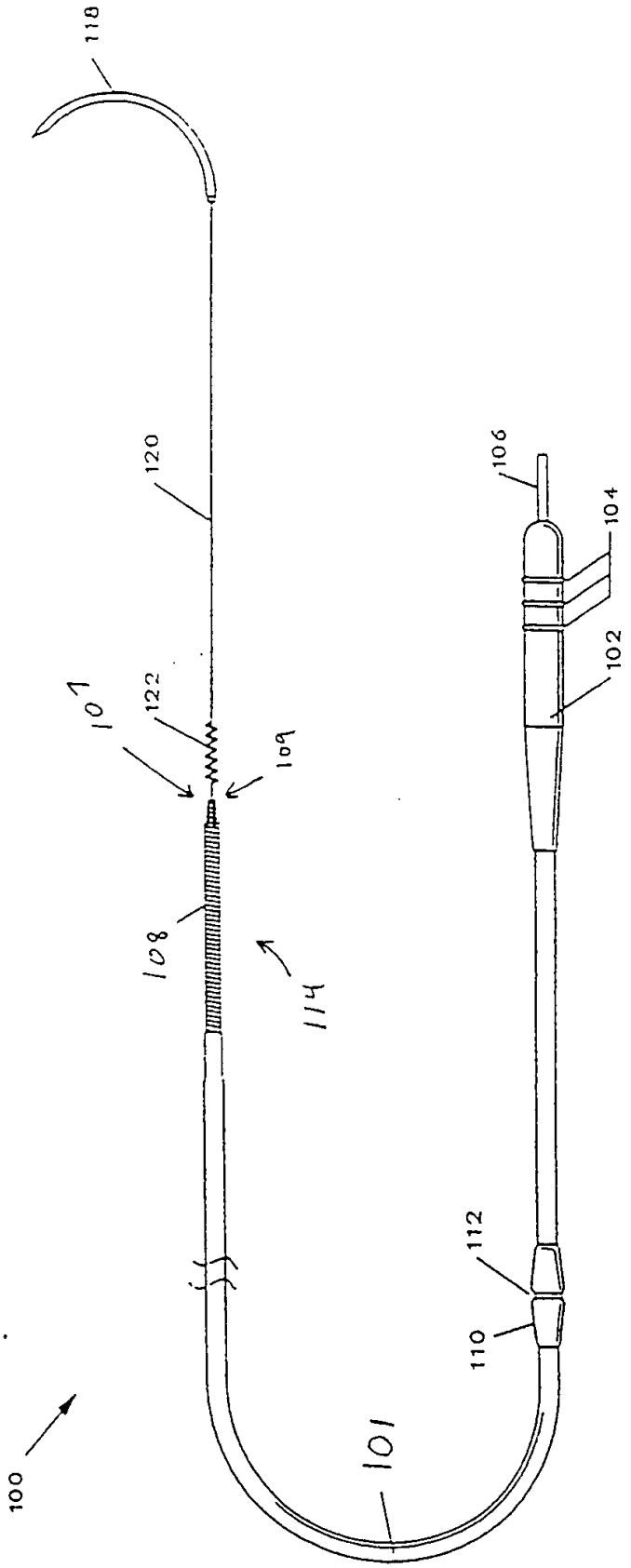
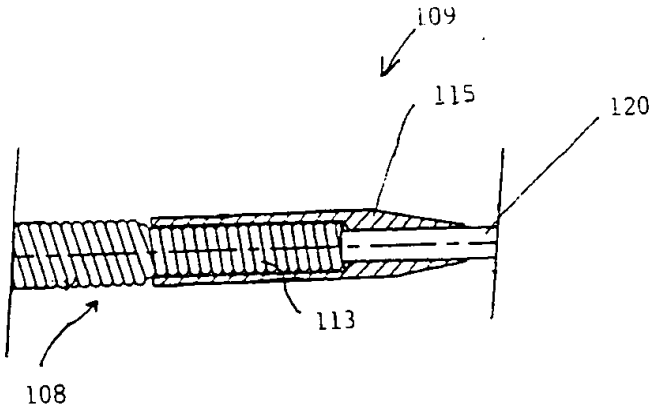


FIG. 2

FIG. 6



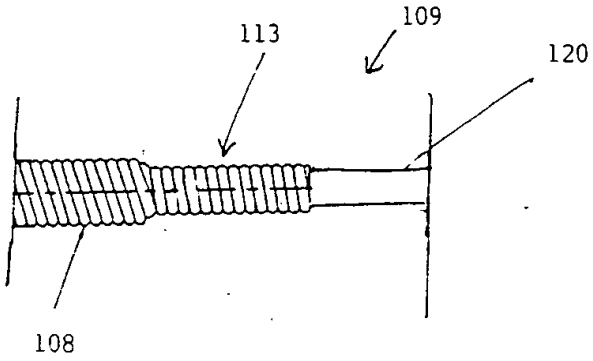


FIG. 4

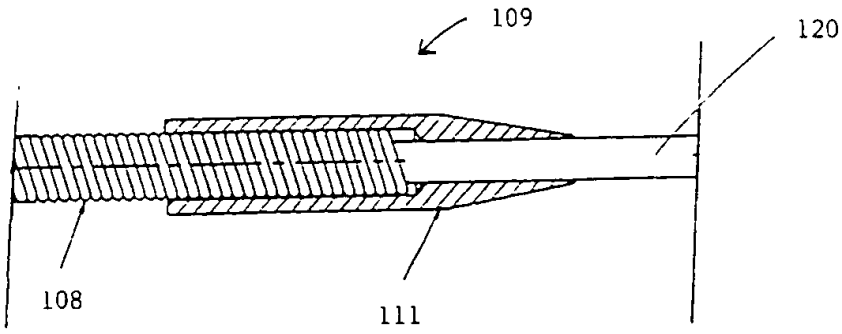


FIG. 3
(Prior art)

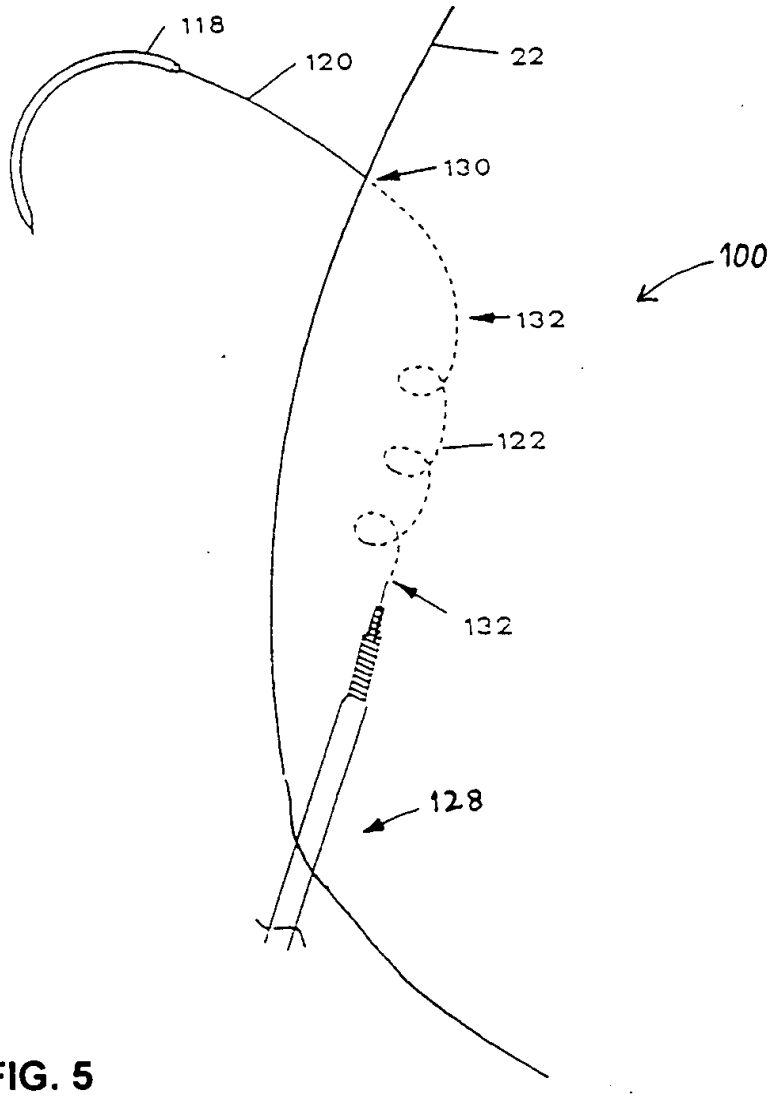


FIG. 5

(19) Europäisches Patentamt
European Patent Office
Office européen des brevets

(11) EP 0 657 185 A3

(12) EUROPEAN PATENT APPLICATION

(88) Date of publication A3:
12.03.1997 Bulletin 1997/11

(51) Int Cl.[6]: **A61N 1/36**, A61N 1/05

(43) Date of publication A2:
14.06.1995 Bulletin 1995/24

(21) Application number: **94309221.3**

(22) Date of filing: **09.12.1994**

(84) Designated Contracting States:
DE FR GB NL

(30) Priority: **09.12.1993 US 164599**

(71) Applicant: **MEDTRONIC, INC.**
Minneapolis, Minnesota 55432-3576 (US)

(72) Inventors:
- **Camps, Antoine**
  NL-6287 NE Eys Wittem (NL)
- **Dreessen, Chrit W.**
  NL-6171 CP Stein (NL)
- **Polz, Michel W.J.**
  NL-6466 XP Kerkrade (NL)
- **Grandjean, Pierre A.**
  B-4608 Warsage (BE)

(74) Representative: **Tomlinson, Kerry John et al**
Frank B. Dehn & Co.,
European Patent Attorneys,
179 Queen Victoria Street
London EC4V 4EL (GB)

(54) Intramuscular lead having improved insertion

(57) An intramuscular lead (100) for the electrical stimulation of muscle tissue. The improved lead has a needle (118) connected to a strand of suture (120), a coiled conductor (108) coupled to the strand by a reduced diameter portion of the coiled conductor, an insulative cover (101) over part of the coiled conductor; and terminal connector means (102) coupled to the coiled conductor to provide a connection to a pulse generator. Through such a construction the lead may be more readily introduced through muscle tissue.

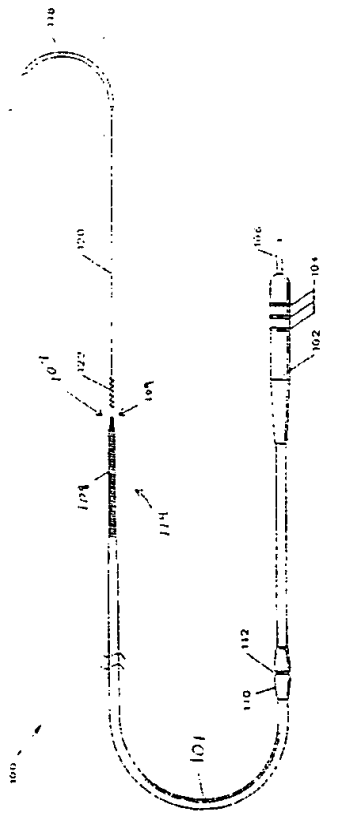


FIG. 2

EP 0 657 185 A3

Printed by Jouve, 75001 PARIS (FR)

European Patent Office

EUROPEAN SEARCH REPORT

Application Number
EP 94 30 9221

DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int.Cl.6)
A	WO 92 15363 A (MEDTRONIC) * the whole document *	1,6-9	A61N1/36 A61N1/05
A,D	US 4 341 226 A (MEDTRONIC) * column 2, line 52 - column 3, line 18 *	1,2,9	
A	DE 28 05 703 A (TRABUCCO) * page 9, line 15 - line 29 *	1	
A	GB 1 174 297 A (BRUNSWICK) * page 2, line 95 - line 108 *	1	

TECHNICAL FIELDS SEARCHED (Int.Cl.6)

A61N

The present search report has been drawn up for all claims

Place of search	Date of completion of the search	Examiner
THE HAGUE	16 January 1997	Lemercier, D

CATEGORY OF CITED DOCUMENTS

X : particularly relevant if taken alone
Y : particularly relevant if combined with another document of the same category
A : technological background
O : non-written disclosure
P : intermediate document

T : theory or principle underlying the invention
E : earlier patent document, but published on, or after the filing date
D : document cited in the application
L : document cited for other reasons

& : member of the same patent family, corresponding document